

DALVANCE[®] (DALBAVANCIN) FOR INJECTION REIMBURSEMENT AT-A-GLANCE

**For more information: Call the DALVANCE CONNECTSSM program
toll-free 1.855.387.2824**

DALVANCE
CONNECTSSM

Program Coordinators are available 8:00 AM to 8:00 PM Eastern time,
Monday through Friday, excluding holidays.

INDICATION AND USAGE

DALVANCE[®] (dalbavancin) for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and methicillin-resistant strains), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus* group (including *S. anginosus*, *S. intermedius*, *S. constellatus*) and *Enterococcus faecalis* (vancomycin-susceptible strains).

To reduce the development of drug-resistant bacteria and maintain the effectiveness of DALVANCE and other antibacterial agents, DALVANCE should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

Contraindications

DALVANCE is contraindicated in patients with known hypersensitivity to dalbavancin.

Please see additional Important Safety Information on page 7.

Please also see enclosed full Prescribing Information.

Site of Service	Drug/ Administration	TYPE OF INSURANCE			
		Medicare	Medicaid	Commercial	Uninsured
Hospital Outpatient Infusion Center (HOPD) Includes: • Emergency Department (ED) • Observation Setting	J0875	J0875, Injection, dalbavancin, 5 mg. Reported as 100 units for a 500 mg vial. J0875 permanent J-code effective January 1, 2016.			DALVANCE CONNECTS SM Patient Assistance Program (PAP) available for eligible patients
	Separate payment for DALVANCE:	Yes, generally paid at Average Sales Price (ASP) + 6%*†	Varies	Varies	
	Payment Methodology	<ul style="list-style-type: none"> Outpatient PPS methodology based on APC system Payment based on rate for APC to which CPT or HCPCS code is assigned Separate payment available for many drugs† Payments can be made for multiple APCs during a single visit 	<ul style="list-style-type: none"> Varies among different states Many states use state-specific fee schedules, <i>per diem</i>/per visit rates, cost, or percentage of charges 	<ul style="list-style-type: none"> Varies among different payors Payment for services: many payors use percentage of charges, negotiated or <i>per diem</i>/per visit rates Payment for drugs: most payors base rates on AWP or ASP 	
	CPT [†] Procedure Code(s) 96365	Drug Administration <ul style="list-style-type: none"> 96365: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour. Medicare payment amounts vary depending on the level of service provided and geographic location - APC code 0439 Level IV Drug Administration. Medicare payment amounts vary depending on the level of service provided Transitional Care Management <ul style="list-style-type: none"> 99201–99205: Office or other outpatient visit, <i>new patient</i>. Medicare payment amounts vary depending on the level of service provided 99211–99215: Office or other outpatient visit, <i>established patient</i>. Medicare payment amounts vary depending on the level of service provided 			

DALVANCE is reimbursed by each unit (5 mg) as defined by the 2016 HCPCS code.

Site of Service	Drug/ Administration	TYPE OF INSURANCE			
		Medicare	Medicaid	Commercial	Uninsured
Free-standing Infusion Center— Physician Office	J0875	J0875, Injection, dalbavancin, 5 mg. Reported as 100 units for a 500 mg vial. J0875 permanent J-code effective January 1, 2016. NOTE: It is the provider's responsibility to report the appropriate HCPCS code based on the payors' requirements.			DALVANCE CONNECTS SM Patient Assistance Program (PAP) available for eligible patients
	Separate Payment for DALVANCE:	Yes, generally paid at ASP + 6%*†	Yes, typically	Yes, typically	
	Payment Methodology	<ul style="list-style-type: none"> Yes, generally paid at ASP + 6%*† Medicare Physician fee schedule for services: fee schedule rate for each CPT or HCPCS code 	<ul style="list-style-type: none"> Varies among different states Payment for services: many states use state-specific fee schedules Payment for drugs: most states base rates on AWP, WAC, or ASP 	<ul style="list-style-type: none"> Varies among different payors Payment for services: most payors use charges, discounted charges, or fee schedules Payment for drugs: most payors base rates on AWP or ASP 	
	CPT [†] Procedure Code(s) 96365	Drug Administration <ul style="list-style-type: none"> 96365: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour. Medicare payment amounts vary depending on the level of service provided 99201–99205: Office or other outpatient visit, <i>new patient</i>. Medicare payment amounts vary depending on the level of service provided 99211–99215: Office or other outpatient visit, <i>established patient</i>. Medicare payment amounts vary depending on the level of service provided 			

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Site of Service	Drug/ Administration	TYPE OF INSURANCE			
		Medicare	Medicaid	Commercial	Uninsured
Hospital Inpatient	J0875	J0875, Injection, dalbavancin, 5 mg. Reported as 100 units for a 500 mg vial. J0875 permanent J-code effective January 1, 2016. NOTE: It is the provider's responsibility to report the appropriate HCPCS code based on the payors' requirements. Revenue codes capture hospital facility cost data by department, which the facility uses for cost reporting purposes. The most commonly used revenue codes for injected/infused products are 0250 (General Pharmacy) and 0636 (Drugs Require Specific ID: drugs requiring detail coding).			<ul style="list-style-type: none"> Uncompensated care for indigent patients may be available Varies by facility
	Separate payment for DALVANCE:	No	Usually not	Usually not	
	Payment Methodology	<ul style="list-style-type: none"> MS-DRG payment for all services 	<ul style="list-style-type: none"> Varies among different states Most states use a PPS such as MS-DRGs or <i>per diems</i> 	<ul style="list-style-type: none"> Varies among different payors Most payors use case rates or <i>per diems</i> 	
	Common MS-DRG Codes	<ul style="list-style-type: none"> MS-DRG 602: Cellulitis with MCC MS-DRG 603: Cellulitis without MCC 			
	Common ICD-10-CM Codes	Cellulitis			
		L03.011-L03.019	Cellulitis of finger		
		L03.031-L03.039	Cellulitis of toe		
		L03.111-L03.119	Cellulitis of other parts of limb		
		L03.211	Cellulitis of face		
		L03.221	Cellulitis of neck		
		L03.311-L03.319	Cellulitis of trunk		
		L03.811-L03.818	Cellulitis of other sites		
		L03.90	Cellulitis, unspecified		
Methicillin-resistant <i>Staphylococcus aureus</i>					
A49.02		Methicillin-resistant <i>Staphylococcus aureus</i> infection, unspecified site			
B95.62		Methicillin-resistant <i>Staphylococcus aureus</i> infection as the cause of diseases classified elsewhere			
<i>Staphylococcus</i>					
A41.01-A41.2		Sepsis due to <i>Staphylococcus</i>			
A49.01		Methicillin-susceptible <i>Staphylococcus aureus</i> infection, unspecified site			
A49.02		Methicillin-resistant <i>Staphylococcus aureus</i> infection, unspecified site			
B95.61-B95.8		<i>Staphylococcus aureus</i> as the cause of diseases classified elsewhere			
<i>Streptococcus</i>					
A40.0-A40.9		Streptococcal sepsis			
A49.1	Streptococcal infection, unspecified site				
B95.01-B95.1, B95.3-B95.8	<i>Streptococcus</i>				

Site of Service	Drug/ Administration	TYPE OF INSURANCE			
		Medicare	Medicaid	Commercial	Uninsured
Home Health	S9494 (describes home infusion for antibiotics that do not have a specific dosing schedule)	S9494 Home infusion therapy, antibiotic, antiviral, or antifungal therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), <i>per diem</i> (do not use this code with home infusion codes for hourly dosing schedules S9497-S9504)			DALVANCE CONNECTS SM Patient Assistance Program (PAP) available for eligible patients
	Separate Payment for DALVANCE:	No	Varies	Varies	
	Payment Methodology	<ul style="list-style-type: none"> Reimbursement based on a 60-day episode of care rate for most services Payment for services: as part of episode of care rate 	<ul style="list-style-type: none"> Varies among different states Most states pay for services and drugs based on <i>per diems</i> Some states may pay separately for drugs based on AWP, ASP, or WAC 	<ul style="list-style-type: none"> Varies among different payors Payment for services: most payors use <i>per diems</i>, case rates, or reasonable cost Payment for drugs: separate payment for drugs is usually provided based on AWP, WAC, or ASP 	
Skilled Nursing Facility/Nursing Home	Separate Payment for DALVANCE:	No	Varies	Varies	
	Payment Methodology	<ul style="list-style-type: none"> Reimbursement based on RUG system, <i>per diems</i>, which include services and drugs 	<ul style="list-style-type: none"> Varies among different states Most states use a prospective payment methodology Separate payment for drugs may be available (including for dual eligible); prior authorization may be required 	<ul style="list-style-type: none"> Varies among different payors Most payors use <i>per diems</i> or percentage of charges If payors pay separately for drugs, payment may be based on AWP, WAC, or percentage of charges 	

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GLOSSARY

APC=Ambulatory Payment Classification; **ASP**=average sales price; **AWP**=average wholesale price; **CPT**=Current Procedural Terminology; **HCPCS**=Healthcare Common Procedure Coding System; **ICD-10-CM**=International Classification of Diseases, Tenth Revision, Clinical Modification; **MCC**=major complication or comorbidity; **MS-DRG**=Medicare Severity Diagnosis-Related Group; **PPS**=prospective payment system; **RUG**=resource utilization group; **WAC**=wholesale acquisition cost

*Coding and payment will vary over time until an average sales price (ASP) is determined and a unique HCPCS code is established.

†The Hospital Outpatient Prospective Payment System's (HOPPS) final rule for Packaging Payment for Drugs, Biologicals, and Radiopharmaceutical Without Pass-Through Status, established a CY 2015 packaging threshold of \$95, effective January 1, 2015.

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IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

Hypersensitivity Reactions

Serious hypersensitivity (anaphylactic) and skin reactions have been reported with glycopeptide antibacterial agents, including DALVANCE. Exercise caution in patients with known hypersensitivity to glycopeptides due to the possibility of cross-sensitivity. If an allergic reaction occurs, treatment with DALVANCE should be discontinued.

Infusion-related Reactions

Rapid intravenous infusion of DALVANCE can cause reactions, including flushing of the upper body, urticaria, pruritus, rash, and/or back pain.

Hepatic Effects

ALT elevations with DALVANCE treatment were reported in clinical trials.

Clostridium difficile-associated Diarrhea

Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including DALVANCE, with severity ranging from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

Development of Drug-resistant Bacteria

Prescribing DALVANCE in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions

The most common adverse reactions in patients treated with DALVANCE were nausea (4.7%), headache (3.8%), and diarrhea (3.4%).

Use in Specific Populations

- There have been no adequate and well-controlled studies with DALVANCE in pregnant or nursing women. DALVANCE should only be used if the potential benefit justifies the potential risk in these populations.
- In patients with renal impairment whose known creatinine clearance is less than 30 mL/min and who are not receiving regularly scheduled hemodialysis, the recommended regimen of DALVANCE is 1125 mg, administered as a single dose, or 750 mg followed one week later by 375 mg. No dosage adjustment is recommended for patients receiving regularly scheduled hemodialysis, and DALVANCE can be administered without regard to the timing of hemodialysis.
- Caution should be exercised when prescribing DALVANCE to patients with moderate or severe hepatic impairment (Child-Pugh Class B or C) as no data are available to determine the appropriate dosing in these patients.

Please see full Indication and additional Important Safety Information on front cover.
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Dalvance[®] 
(dalbavancin) for injection
500 mg



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